

### Use of Gold Nanoparticles is the key advantage of 2<sup>nd</sup> generation Covid-19 Rapid Antibody Tests.

The 2<sup>nd</sup> generation development of the Covid-19 Rapid Antibody IgM/IgG test has seen the **introduction of gold nanoparticles** into the testing strip. This is called the **Colloidal Gold Method**.

#### The Gold Nanoparticle Advantage

Gold nanoparticles are tiny, 2,500 would fit across the width of a human hair. They are coated with substances (conjugates) that detect the presence of the IgM and IgG antibodies, which your body produces if you get Covid-19. Because the gold nanoparticles are so tiny, the surface-to-volume ratio is high and it is **this colloidal gold characteristic that is exploited to improve accuracy**. The **more surface area** of conjugate there is for the antibodies to attach to, the **better the detection** success. This is called **the Colloidal Gold Method** and is used widely in the disease testing industry. We have no studies to hand, or found in our searches, that quantifies the improvement specifically for the first generation Covid-19 Rapid test to the second generation Covid-19 Rapid test Colloidal Gold Method. However, we include two published article extracts below that have studied the improvement gained from migrating to the Colloidal Gold Method in disease testing. One study showed a **1,000-fold increase** in improvement in sensitivity and the other, which was detecting a pneumonia virus in mice, showed a **3,000-fold increase in detecting IgGs**. While these significant **improvements cannot be read across directly** to the Covid-19 Rapid tests, they might serve as a guide for the level of improvement in the Covid-19 Rapid test with the addition of the Colloidal Gold Method. For further reference, it is not uncommon for the World Nano Foundation to see this magnitude (i.e.1,000 to 10,000-fold) of improvement when nanotechnology comes to bear on older technologies.

#### The Coating on the Gold Nanoparticles is a point of difference

The coating substances (conjugates) on the gold nanoparticles are **different from manufacturer to manufacturer**. The selection of the source chemistry for making the conjugates is made as a result of trialling different solutions that are designed based on the DNA of Covid-19. We believe that these conjugates are **proprietary to the developers of the tests**.

#### Implications for testing when using the Colloidal Gold Method

Some manufacturers' claims that the test results are **reliable after 3 days** of the IgM reaction to the Covid-19 virus is given credence by the implied significant increase in Covid-19 test sensitivity as a direct result of the introduction of the Colloidal Gold Method in the 2<sup>nd</sup> generation tests. This shows Covid-19 Rapid Antibody Test by Colloidal Gold Method can be a **valuable POC (Point-Of-Care) aid to help** identify people who have the Covid-19 infection or have had the infection. This is vital in the fight to **slow down the spread of the disease**. Importantly, 2<sup>nd</sup> generation tests give three possible positive results (definitively IgM only, IgM & IgG or IgG only). These distinct answers, when part of a diagnostic protocol, can establish which phase of the infection the person is in. This is vital for making policy decisions on when **people can go safely back to work**, as they are henceforth non-contagious and immune.

The 2<sup>nd</sup> generation Covid-19 Antibody test by Colloidal Gold Method is **more accurate, more informative and more reliable**.

**Extracts from Academic Papers.**

“Nanodiagnosics, defined as the use of nanotechnology in diagnostic applications, has been extensively studied to meet the requirements of clinical diagnostics with high sensitivity and earlier detection of various diseases. The high surface-to- volume ratio of nanostructures makes them very suitable to attach lots of targeting molecules that improve the sensitivity of the detecting results. The unique properties of nanomaterials or nanostructures confer the nanodiagnostic platforms on an ability of rapid and real-time detection by only using very small volumes of samples from patients. Thus, nanodiagnostic approaches have huge potential to be low-cost, user-friendly, and robust systems.”<sup>1</sup>

“A new approach to ultrasensitive detection of DNA hybridization based on nanoparticle-amplified surface plasmon resonance (SPR) is described. Use of the Au nanoparticle tags leads to a greater than 10-fold increase in angle shift, corresponding to a more than 1000-fold improvement in sensitivity for the target oligonucleotide as compared to the unamplified binding event.”<sup>2</sup>

“Furthermore, we have successfully used GNP-ELISA to highly improve the detection (~3,000-fold) of specific IgGs against *S. pneumoniae* in mice sera respect to the BSA-based ELISA.”<sup>3</sup>

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<sup>1</sup> Application of nanodiagnosics in point-of-care tests for infectious diseases (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5503494/>)

<sup>2</sup> Colloidal Au-Enhanced Surface Plasmon Resonance for Ultrasensitive Detection of DNA Hybridization (<https://pubs.acs.org/doi/10.1021/ja001215b>)

<sup>3</sup> High Sensitive Detection of Carbohydrate Binding Proteins in an ELISA-Solid Phase Assay Based on Multivalent Glyconanoparticles (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3754922/>)